


blood coagulation inhibitors and contains no more than approximately 5% of activated blood coagulation factor VII.

21. (Amended) The stable pharmaceutical preparation of claim 20, wherein said blood coagulation factor VII has a protease activity, when activated, of greater than 100 Units/mg of total protein.

 22. (Amended) The stable pharmaceutical preparation of claim 20, wherein said blood coagulation factor VII is present in an amount of between approximately 5 U/mL to approximately 5,000 U/mL.

23. (Amended) The stable pharmaceutical preparation of claim 20, wherein said preparation is lyophilized.


24. (Amended) The stable pharmaceutical preparation of claim 23, wherein said preparation is stable for at least 12 hours after reconstitution.

25. (Amended) The stable pharmaceutical preparation of claim 20, wherein said blood coagulation factor VII is a recombinant protein.

26. (Amended) The stable pharmaceutical preparation of claim 20, wherein said blood coagulation factor VII is recovered from normal human plasma.

27. (Amended) The stable pharmaceutical preparation of claim 26, wherein said blood coagulation factor preparation has no detectable transmissible human pathogens.

28. (Amended) A method for preparing a stable pharmaceutical preparation comprising:

 absorbing blood coagulation factor VII from a biological material onto a chromatographic substrate;

selectively eluting said absorbed blood coagulation factor VII from said chromatographic substrate using a blood coagulation inhibitor-free elution buffer; and

selecting an eluate having a protease activity of at least 50 U/mg of total protein, when activated, and wherein the pharmaceutical preparation contains no more than approximately 5% activated blood coagulation factor VII.

29. (Amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said elution buffer has a pH of between approximately 5.0 to approximately 9.0.

30. (Amended) The method for preparing a stable pharmaceutical preparation of claim 29, wherein said elution buffer has a pH of between approximately 6.0 to approximately 7.5.

31. (Amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said chromatographic substrate is an anion exchange material and said selective elution being performed using a chromatography column and a chromatography column flow rate of at least 0.15 column volumes per minute.

B' 32. (Amended) The method for preparing a stable pharmaceutical preparation of claim 31, wherein said flow rate is between approximately 0.17 to 2.0 column volumes per minute.

33. (Amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said chromatographic substrate is an immunoaffinity column specific for factor VII.

34. (Amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said chromatographic substrate is a material having hydrophobic groups.

35. (Amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said chromatographic substrate is a hydrogel.

36. (Amended) The method for preparing a stable pharmaceutical

preparation of claim 28, wherein said biological material is selected from the group consisting of blood, plasma, a plasma fraction, a cell culture and a cell culture fraction.

B / 37. (Amended) The method for preparing a stable pharmaceutical preparation of claim 31, further comprising absorbing said eluate having a protease activity of at least 50 U/mg of total protein onto a second chromatographic substrate having hydrophobic groups and selectively eluting said absorbed eluate from said chromatographic substrate having hydrophobic groups.

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40. (Amended) A stable pharmaceutical preparation comprising:  
blood coagulation factor VII having a protease activity, when activated, of at least 50 U/mg of total protein, wherein said blood coagulation factor preparation is free from blood coagulation inhibitors and contains no more than approximately 5% of activated blood coagulation factor VII ; and  
B2 at least one additional coagulation factor.

41. (Amended) The stable pharmaceutical preparation of claim 40, wherein said additional blood coagulation factor is selected from the group consisting of factor II, factor IX and factor X.

42. (Amended) A method for preparing a stable pharmaceutical preparation comprising:

absorbing blood coagulation factor VII from a biological material onto an anionic chromatographic column;

selectively eluting said absorbed blood coagulation factor VII from said chromatographic column at a flow rate of between approximately 0.17 to 2.0 column volumes per minute using a blood coagulation inhibitor-free elution buffer having a pH of between approximately 6.0 to 7.5; and

selecting an eluate having a [protease activity of at least 50 U/mg of total protein, when activated, and wherein the pharmaceutical preparation contains no more than approximately 5% activated blood coagulation factor VII.

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43. (Amended) The method for preparing a stable pharmaceutical preparation of claim 42, wherein said biological material is selected from the group consisting of blood, plasma, a plasma fraction, a cell culture and a cell culture fraction.

44. (Amended) The method for preparing a stable pharmaceutical preparation of claim 42, further comprising absorbing said eluate having a protease activity of at least 50 U/mg of total protein onto a second chromatographic substrate having hydrophobic groups and selectively eluting said absorbed eluate from said chromatographic substrate having hydrophobic groups.

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